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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/003,869	01/07/1998	NIGEL ROBERT ARNOLD BEELEY	030639.0043.CPA1	9574

7590 03/05/2003

ARNOLD & PORTER
Attn: IP Docketing Department, Room 1126B
555 Twelfth Street, NW
Washington, DC 20004-1206

EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	35

DATE MAILED: 03/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/003,869	BEELEY ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *23,28,31* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT OF AMENDMENT, REMARKS, IDS, DRAWINGS AND STATUS OF HE CLAIMS

1. The amendment and remarks filed 11/13/02, the information disclosure statements (IDS) and Form PTO-1449 filed 5/28/02, 11/1/02 and 11/13/02, and the corrected drawings filed 9/16/02, respectively are acknowledged, entered and considered. In view of Applicant's request claims 5-6, 20-22 and 32-33 have been amended and claims 23-30 and 34 have been canceled. Thus, claims 1-22 and 32-33 are now pending in the application. The rejections under 35 U.S.C. 112, first paragraph, 35 U.S.C. 112, second paragraph, 35 U.S.C. 102(b) and 35 U.S.C. 103(a) over the prior art of record are withdrawn in view of Applicant's amendment, remarks, and cancellation of claims filed 11/13/02.

The following is a new ground of rejection:

NEW GROUND OF REJECTION

CLAIMS REJECTION-35 U.S.C. §103(a)

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navarro et al. (Journal of Neurochemistry, Vol. 67, No. 5, pp. 1982-1991, 1996) taken with Eng (U.S. Patent No. 5,424,286) and WO 96/40196.

Navarro et al. teach the intracerebroventricular (I.C.V.) administration of GLP-1 (7-36) amide in combination with exendin-3 and exendin-4 in a broad range of doses (0.2, 1, 5, 25, 100 and 500 ng) which resulted in marked decrease of both food and water intake (See e.g., abstract, page 1984, right column under Experimental Design, and page 1986, right column) as directed to claims 1-8, 10-11, 14-18 and 20-22. On page 1986, right column, the reference clearly shows that using *in vivo* system of both exendin-4 and exendin (9-39) interact with the GLP-receptor of the rat brain in proving that their use would result in controlling food and water intake that affect satiety reduced food intake and body weight in rodents.

The reference of Navarro et al. differs from claims 1-22 and 32-33 in failing to teach the use of various exendin and exendin antagonists including amylin agonist and CCK for treating conditions or disorders which include obesity, diabetes, eating disorders, insulin resistance syndrome, lowering the plasma glucose level, lowering the plasma lipid level, reducing the cardiac risk, and reducing the appetite of the subject". However, the secondary reference of Eng (U.S. Patent No. 5,424,286) teaches a pharmaceutical composition comprising exendin-3 or exendin-4, fragments thereof, or any combination thereof for treatment of diabetes mellitus and the prevention of hyperglycemia (See e.g., Abstract and Summary of the Invention) as directed to claims 9 and 12. The '286 patent on col. 4, lines 66 to col. 5, lines 19, states that the compounds of the present invention (i.e., exendin-3 and or exendin-4, or their functional derivatives combined in admixture with a pharmaceutically acceptable carrier vehicle) can be formulated according to known methods to prepare pharmaceutically useful compositions which may be injected intravenously, intramuscularly, subcutaneously, or intraperitoneally, would call for dosages of about 0.1 pg/kg to 1,000 mg/kg body weight depending on many individual factors such as age, severity of disease, total body weight, sex, and other mitigating factors. Thus, clearly showing that the use of exendin-3 and exendin-4 as insulinotrophic agents for the treatment of diabetes mellitus and the prevention of hyperglycemia. Further, the patent of WO 96/40196 discloses compositions and methods for reducing food intake, suppressing appetite and controlling body weight by administering compositions comprising an amylin agonist and a CCK (See abstract and Summary of the Invention) as directed to claims 19 and 32-33.

Thus, the secondary references clearly teach the use of exendin or exendin antagonist including amylin agonist and CCK for treatment of diabetes and prevention of hyperglycemia (i.e, lowering the plasma glucose level) and reducing food intake, suppressing appetite and controlling body weight. Although, the secondary reference of Eng does not teach a method for reducing food intake and body weight in a subject; however, such metabolic intervention intended to an effective treatment to reduce food intake and body weight is taught by the primary reference of Navarro et al., and the secondary reference of WO 96/40196. Therefore, given the teachings of the secondary reference of Eng, one of ordinary skill in the art would have been motivated to adapt the above scheme of using exendin or exendin antagonist alone or in combination with other compounds or composition that affect satiety, because such features are known in the art. Hence, including such features into the composition of the primary reference in view of secondary references, would have obvious to one having ordinary skill in the art to obtain the known and recognized functions and advantage thereof.

With respect to the amount of dosages, although each of the prior art clearly discloses the use of broad ranges of dosages; the prior art does not teach the dosages in the manner claimed; however, it would be conventional and within the ordinary skill in the art to which this invention pertains to select the appropriate optimum dosage of specific exendin or exendin antagonist peptide for the intended purpose of formulating a therapeutically effective pharmaceutical composition. Thus, in view of this, the subject composition may be used in combination with other materials to provide a wide variety of applications or may be tailored for specific

applications, absence of sufficient objective factual evidence or unexpected results to the contrary.

OBJECTION TO CLAIMS

3. Claims 19 and 32-33 are objected in the recitation the acronym "CCK". Use of the full terminology at least in the first occurrence would obviate this objection.

CONCLUSION AND FUTURE CORRESPONDENCE

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 5:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Mohamed/AAM

February 27, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600